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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------------|----------------------------|-------------------------|------------------|
| 10/699,014 | 10/31/2003 | David Christopher Majercak | CRD-5057 | 1422 |
| 27777 | 7590 09/19/2005 | | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON | | | GHERBI, SUZETTE JAIME J | |
| ONE JOHNSON & JOHNSON PLAZA | | | ART UNIT | PAPER NUMBER |
| NEW BRUN | SWICK, NJ 08933-7003 | | 3738 | |

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|---|--|---|---|---|--|--|
| Office Action Summary | | 10/699,014 | MAJERCAK ET AĻ. | | | |
| | | Examiner | Art Unit | | | |
| | | Suzette J. Gherbi | 3738 | | | |
| Period fo | The MAILING DATE of this communication app or Reply | ears on the cover sheet with the c | orrespondence address | | | |
| WHIC - Exte after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS OF THE MAILING DANSIONS OF THE MAY BE AVAILABLE OF THE MAILING DANSIONS OF THE MAILING DANSIONS OF THE MAILING DANSIONS OF THE MAILING THE MAIL | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | I. lely filed the mailing date of this communication. O (35 U.S.C. § 133). | | | |
| Status | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 30 Ju | <u>ıne 2005</u> . | | | | |
| 2a) | This action is FINAL . 2b)⊠ This | action is non-final. | | | | |
| 3) 🗌 | Since this application is in condition for allowar | nce except for formal matters, pro | secution as to the merits is | | | |
| | closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 45 | 33 O.G. 213. | , | | |
| Disposit | ion of Claims | | | | | |
| 4) 🖂 | ☑ Claim(s) <u>2-22,24,25,28,30,31 and 36</u> is/are pending in the application. | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5)⊠ | Claim(s) <u>2-22, 24, 25, 28, 30 and 31</u> is/are allowed. | | | | | |
| 6)⊠ | Claim(s) <u>36</u> is/are rejected. | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | |
| 8) | Claim(s) are subject to restriction and/or | r election requirement. | | | | |
| Applicat | ion Papers | | | | | |
| 9) | The specification is objected to by the Examine | r. | • | | | |
| 10) | 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | |
| | Applicant may not request that any objection to the | drawing(s) be held in abeyance. See | e 37 CFR 1.85(a). | | | |
| | Replacement drawing sheet(s) including the correct | ion is required if the drawing(s) is obj | ected to. See 37 CFR 1.121(d). | | | |
| 11) | The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152. | | | |
| Priority ι | under 35 U.S.C. § 119 | | • | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| | 1. Certified copies of the priority documents | | on No | | | |
| | 2. Certified copies of the priority documents3. Copies of the certified copies of the priority | * * | | | | |
| | application from the International Bureau | | d III tilis National Stage | | | |
| * 5 | See the attached detailed Office action for a list | | d. | | | |
| | | · | | | | |
| Attachmen | | | | | | |
| | e of References Cited (PTO-892) | 4) Interview Summary | (PTO-413) | | | |
| 2) Notic | e of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | te | | | |
| . — | mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date | 6) Other: | atent Application (PTO-152) | | | |

DETAILED ACTION

1. Applicant's amendment dated 6/30/05 has been received in application serial number 10/699,014. Claims 1, 23, 26-27, 29, 32-35 have been canceled.

Response to Arguments

2. Applicant's arguments and amendment filed June 30, 2005 with respect to the rejection(s) of claim(s) 1-6, 8-22, 24-25, 28, and 30-31 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration and discovery of a related application (10/699,295 filed 10/31/03, a new ground(s) of rejection is being made.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huter et al. 6,511,496 in view of Quijano et al. 5,500,014. Huter discloses the invention as claimed comprising: A radially expandable structural frame defining a longitudinal axis,

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including an anchor structure having first and second open ends. (24) a connecting member (22) having a first end and a second end, the first end of the connecting member being attached to the second end of the anchor structure, and a cantilever valve strut (see marked up copy) having first and second ends, the first end of the cantilever valve strut being cooperatively associated with the second end of the connecting member; and a biocompatible membrane (col. 7, lines 45-49) assembly having a substantially tubular configuration disposed longitudinally about the structural frame. However Huter does not specify that the membrane is made from a vein material. Quijano et al. teaches that venous graft material can be utilized in valve devices. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the membrane of Huter et al. an utilize a biological vein material such as that taught by Quijano et al because the natural tissue would resist rejection that sometimes comes with synthetic materials and would more closely mimic the surrounding tissue and blood flow. It is also obvious to one having ordinary skill in the art that because Huter has a membrane with a first end with a first diameter and a second end having a second diameter wherein the first diameter endr is greater than the second diameter end (see figure 2, 7 and 8.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

- 6. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
- 7. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).
- 8. Claim 36 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/699,295. Current claim 36 has the same limitations of claim 1 and 7 and it is obvious that a first end having a first diameter and a second end having a second diameter is substantially equivalent and re-worded as in claim 1 of copending application as "a first open end and a second closed end" where these are the two diameters. This is a <u>provisional</u> obviousness-type double patenting rejection.

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Allowable Subject Matter

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9. Claims 2-22, 24-25, 28, 30-31 are allowed.

Conclusion

- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.
- 11. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.
- 12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Suzette J-J Gherbi 14 September 2005